

In the Specification:

Please amend the specification of the above-identified application as follows. References are to the English translation of the application.

Please insert at page 1, lines 1-5 the following:

Related Applications

Benefit of priority is claimed under 35 U.S.C. 119(e) to German Application No: DE 103 48 550.3-41 filed on October 20, 2003 and to International Application No: PCT/EP2004/011875 filed on October 20, 2004. The disclosures of the above-referenced applications are fully incorporated by reference.

Please delete the paragraph at p. 2, line 34 – p.3, line 4 and replace it with the following:

EP-A-0 373 679 discloses that G-CSF may be kept stable over a prolonged period of time when formulated in solutions having a pH value of 2.75 to 4.0 whose conductivity is advantageously as low as possible. Preferably, no buffer is used in these formulations in order to avoid the aggregation of G-CSF, however carboxylic acids, citric acid, lactic acid or tartaric acid may be used in small amounts of less than 2 mM as buffer substances. Stable formulations having pH values near the ~~physiologic~~ physiological pH value, however, are not possible under these conditions.

Please delete the paragraph at p. 5, lines 1-2 and replace it with the following:

Further embodiments of the invention are apparent from the claims and from the following description and are not limited to the embodiments disclosed above.

Please delete the paragraph at p.7, lines 6-16 and replace it with the following:

The pH value of the compositions according to the invention is usually between 3.5 and 6.0, for example between 4.0 and 5.9. Preferably the pH is higher than 4.0 and, ~~[[foe]]~~ for example, is between 4.1 and 5.7, in particular between 4.2 and 5.5, for example between 4.5 and 5.5. If desired, the pH value may additionally be adjusted to the desired value using other acids and bases. Suitable acids are, for example, hydrochloric acid, phosphoric acid, acetic acid, citric acid, and sodium or potassium dihydrogen phosphate. Suitable bases are, for example, alkali and alkaline earth hydroxide, alkali carbonates, alkali acetates, alkali citrates and dialkali hydrogen phosphate, e.g., sodium hydroxide, sodium acetate, sodium carbonate, sodium citrate, disodium and dipotassium hydrogen phosphate as well as ammonia.

Please delete the paragraph at p.9, lines 23-32 and replace it with the following:

The preparation of the compositions according to the invention may take place in a manner known ~~[[per]]~~ ~~[[se]]~~ to a practitioner of reasonable skill in the art. Usually, the buffer substances and, optionally, the additional stabilizers and/or the adjuvants and inactive ingredients are first dissolved in suitable amounts in the aqueous solvent, usually sterile water. If necessary, the pH value is adjusted using succinate and/or tartrate solutions or using other acids or bases, such as those mentioned above as examples. Following a usual sterilization step, such as filtration through a sterile filter, G-CSF is added in the desired concentrations. It is also possible, however, to first provide G-CSF in an aqueous solution and then to adjust the pH to the desired value with succinate and/or tartrate.

Please delete the paragraph at p.10, lines 10-20 and replace it with the following:

Furthermore, another object of the present invention are G-CSF-containing lyophilisates and powders comprising succinate and/or tartrate in the form of the free acid and/or of a salt thereof. Such lyophilisates and powders may be obtained, for example, from the above described aqueous compositions in a manner known ~~[[per]]~~ ~~[[se]]~~ to those of reasonable skill in the art simply by lyophilization or, e.g., by spray-drying. In these lyophilisates and powders, G-CSF, succinate and/or tartrate as well as optionally further buffer substances, stabilizers and adjuvants and inactive ingredients are present in such amounts that upon dissolving once again in water, G-CSF-containing compositions are obtained which are stable over a prolonged period of time even at elevated temperatures similar to the corresponding aqueous compositions.

Please delete the paragraph at p.19, lines 4-6 and replace it with the following:

SCF instant syringes (Becton Dickinson, Grenoble, ~~Frankreich~~ France) were charged with 500 µl samples of the prepared compositions and agitated for 10 sec at room temperature on a Vortex[®] apparatus for generating mechanical stress.